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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,761	03/25/2004	Charles R. Stewart	31175413-004002	8658

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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,761	STEWART, CHARLES R.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12/09/2005

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15,17,19,20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15,19,20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *06 March 2006* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 11-15, 19, 20 and 22-24 are pending and under examination. Claim 17 is withdrawn from further consideration. In a phone call with Dr. Michael Berger, on 06 March 2006, claim 17 has been agreed upon to be withdrawn from consideration. The claim is inconsistent with the elected subject matter as it is drawn to a method of inhibiting bacteria by administering a bacteriophage vector rather than a protein (see Interview Summary for further details). Claim 12 is limited to the election of administration of a protein and the bacteriophage and expression vector are withdrawn from consideration.

Inventorship

2. The correction of inventorship filed by applicants is confusing as it cites the correction of inventor ship of the provisional application. The guidelines below, for deletion of an inventor in both a provisional and non-provisional must be strictly adhered to if Applicant's would like to delete Dr. Shamoo as a named inventor.

> Deletion of an inventor from a provisional application, 37 C.F.R. 1.48(e):
>
> Provisional application —deleting the name or names of the inventor or inventors. If a person or persons were named as an inventor or inventors in a provisional application through error without any deceptive intention on the part of such person or persons, an amendment may be filed in the provisional application deleting the name or names of the person or persons who were erroneously named. Amendment of the inventorship requires:
> (1) A request to correct the inventorship that sets forth the desired inventorship change;
> (2) A statement by the person or persons whose name or names are being deleted that the inventorship error occurred without deceptive intention on the

part of such person or persons;
(3) The processing fee set forth in § 1.17(q); and
(4) If an assignment has been executed by any of the original named inventors, the written consent of the assignee.

Deletion of an inventor from a non-provisional application, 1.48(a):

Nonprovisional application *after* oath /declaration filed . If the inventive entity is set forth in error in an executed § 1.63 oath or declaration in a nonprovisional application, and such error arose without any deceptive intention on the part of the person named as an inventor in error or on the part of the person who through error was not named as an inventor, the inventorship of the nonprovisional application may be amended to name only the actual inventor or inventors.
Amendment of the inventorship requires:
(1) A request to correct the inventorship that sets forth the desired inventorship change;
(2) A statement from each person being added as an inventor and from each person being deleted as an inventor that the error in inventorship occurred without deceptive intention on his or her part;
(3) An oath or declaration by the actual inventor or inventors as required by § 1.63 or as permitted by §§ 1.42, 1.43 or § 1.47;
(4) The processing fee set forth in § 1.17(i); and
(5) If an assignment has been executed by any of the original named inventors, the written consent of the assignee.

Withdrawn Objections and Rejections

Claim Rejections - 35 USC § 103

3. The rejection of claims 11-15 and 17-20 as being unpatentable over Wie et al. is hereby withdrawn.

4. The rejection of claims 11-15, 17-20 and 22-25 as anticipated, or in the alternative, obvious over Sampath et al. (Section 12 of the previous Office action) is hereby withdrawn in view of Declaration submitted under 37 C.F.R. 1.132 which removes Sampath et al. as prior art.

Maintained Objections and Rejections

Claim Objections

5. Claims 11, 13-14, 20 and 22-25 are objected to because of the following informalities: The claims still contain non-elected subject matter, sequences other than SEQ ID No: 8.

Response to Arguments

6. Applicant's arguments, see the Remarks, pages 5 and 6, filed 09 December 2005, with respect to the lack of *prima facie* obviousness of the claims in view of Wie et al. have been fully considered and are persuasive. The rejection of claims 11-15 and 17-20 has been withdrawn. The rejection of claims 11-15, 17-20 and 22-25 under 35 U.S.C. 103(a) are also withdrawn in view of the 37 C.F.R. 1.132 declaration.

New Objections and Rejections

Claim Rejections - 35 USC § 112 – 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11-15, 19-20 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of inhibiting a bacterial infection in a mammal by administering a polypeptide according to SEQ ID No: 8 in order to inhibit said infection in said mammal. However, the specification is drawn exclusively to inhibition of a bacterial infection by administering DNA which encodes the SEQ ID No: 8, and does not provide any examples or direction of how the administration of "naked" protein will result in the same inhibition as when delivered by a completely different route, that being DNA. Thus, a skilled artisan, armed with the knowledge that administration of foreign proteins feasibly will elicit an immune response triggering the immediate attack and breakdown of said proteins, would have to devise their own *de novo* methods of how to use the invention in order to practice it. Furthermore, *even if*, the proteins/peptides were not broken down, there is no guidance of how these proteins would find said bacteria, and then be able to traverse the bacterial cell membrane. It is specifically reported in the specification that these proteins function exclusively by shutting off host-DNA synthesis, thus, the proteins would necessarily have to be able to make their way into the bacterial cell. However, this point is neither addressed nor even mentioned, and certainly has not been practiced by Applicants. Furthermore, it is also well known in the art that various modes of *in vivo* administration to mammals will work while others will not. However, no route of administration has been tested by Applicants at all. Finally, SEQ ID No: 8 is protein that functions by binding DNA and shutting off host replication function. Thus, SEQ ID No: 8, which is a nuclear protein, would have to

traverse not only the bacterial cell membrane, but traverse the cytoplasm and then also traverse the nuclear membrane as well. How this might be achieved is limited in the specification to phage vector therapy and it is not addressed how a "naked" protein would work. Thus those skilled in the art would be left to work out the missing details *de novo* in order to make and use the invention and this is seen as both burdensome and undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary.

The claims are generically drawn to a method of inhibiting bacterial infection in a mammal by administering the protein according to SEQ ID No: 8. However, the complexity of inhibiting bacterial infection is not a simple one. The route of administration can have a direct effect on success, but one of the main hurdles for inhibition to occur in a mammal is the transport of the peptide into the bacterial cell. SEQ ID No: 8 will not passively find its way through the eukaryotic system and passively transport *into* the bacterial cell without at least some sort of peptide signal sequence, or some other means of gaining entry into the cell. This is highlighted in the prior art where short peptides are added to the antibiotic aminomethyl tetrahydrofuranly (THF)-1β-methylcarbapenems in order to enhance absorption by making use of a petide-mediated transport system (Wiess et al. Antimic. Agents and Chemotherapy, 1999, 43(3):460). THF differs from the present invention in that is a chemical compound and not bound to gaining entry by active transport, the compound can passively traverse the bacterial cell membrane. However, this is contrary to SEQ ID No: 8, which is a protein and necessarily is bound to traversing the bacterial cell membrane via an artificial means which is not disclosed in the specification, then traversing the cytoplasm without being degraded and finally traversing the nuclear membrane to get to its destination and bind the DNA in order to shut-off the bacterial biosynthesis. There is no expectation of success in this instance because there would be absolutely no certainty or anticipation that a nuclear protein such as SEQ ID No: 8 would have a means for translocating the bacterial outer cell membrane to get into the cell. The complications of moving through the cytoplasm also would subsequently present significant problems in itself. The

amount of guidance in the specification is significant, but only in administering SEQ ID No: 8 via a phage or vector, (e.g. disguising it as DNA) which is a well known mechanism for delivering antibiotics and other drugs in mammals. Nonetheless, there is zero guidance in the specification or examples to teach one skilled in the art how to inhibit a bacterial infection in a mammal by administering a protein according to SEQ ID No: 8. Despite the very high skill level of one of ordinary skill in the art, the problems expected to be encountered by said skilled artisan would be significant and not trivial. Thus, it would be expected that a skilled artisan would have to endure considerable unnecessary experimentation in order to practice the claimed invention.

Thus the claims as stated as such are a mere invitation to a skilled artisan to perform extensive and undue experimentation in order to make and use the claimed invention which is exemplified when Wands analysis and factors are considered in their entirety.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMN
6 March 2006

JON WEBER
SUPERVISORY PATENT EXAMINER